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Cardiopulmonary exercise testing before and after blood transfusion

Submission date	Recruitment status	[_] Prospectively registered
28/12/2010	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
05/04/2011	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
22/02/2019	Haematological Disorders	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
5563

Study information

Scientific Title
Cardiopulmonary exercise testing before and after blood transfusion: a prospective clinical study

Study objectives
That a blood transfusion has no effect on a patient's ability to exercise as judged by Cardio-Pulmonary Exercise Testing (CPX) testing.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration

Study design
Single-centre prospective clinical study

Primary study design
Interventional

Secondary study design
Non randomised study

Study setting(s)
Hospital

Study type(s)
Other

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied
Anaemia

Interventions
Blood transfusion:
1. We are investigating anaemic haematology patients and determining their exercise capacity before and after transfusion by means of cardio-pulmonary exercise testing
2. Each patient will undergo exercise testing twice before transfusion (1-3 days before and on the day of transfusion) and once afterwards (3-5 days after)
3. A blood sample to check Hb concentration will be undertaken at the time of each test
4. Comparing the results of tests one and two will allow us to determine the intra-patient variability of the test in this population, while comparing tests two and three will allow us determine the physiological effects of transfusion

Intervention Type
Other

Phase

Not Specified

Primary outcome measure
The change in anaerobic threshold following blood transfusion

Secondary outcome measures
1. The change in AT per unit (g/dL) change in Hb concentration will be determined to correct for the variable change in Hb seen with blood transfusion
2. Changes in other CPX variables following transfusion, including peak VO2, OEUS (Oxygen Efficiency Utilisation Slope), Ve/VCO2 ratio, VO2/HR ratio and Respiratory Exchange Ratio (RER)
3. Intra-patient variability in the AT measured by CPX testing will be expressed as the coefficient of variation

Overall study start date
01/02/2011

Completion date
01/08/2011

Eligibility

Key inclusion criteria
1. Patients requiring blood transfusion under the care of the haematology team
2. Patients over the age of 18 years
3. Capacity to give informed consent
4. Comprehension of English
5. Ability to undertake CPX testing using a cycle ergometer

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
28

Key exclusion criteria
1. A requirement to have an urgent blood transfusion as judged by the haematologist caring for the patient. (This would not allow sufficient time to undertake proper consent and perform CPX tests one and two).
2. Ongoing active bleeding
3. Those who get angina or intermittent claudication on moderate exercise or who have shortness of breath at rest

4. Patients who have a significant acute medical illness
5. Those with other contraindications to exercise testing according to the ACC/AHA Exercise Testing Guidelines or our own local guidelines

Date of first enrolment
01/02/2011

Date of final enrolment
01/08/2011

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Department of Haematology
Newcastle upon Tyne
United Kingdom
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Sponsor information

Organisation
Royal Victoria Infirmary Newcastle (UK)

Sponsor details
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Sponsor type
Hospital/treatment centre

ROR

https://ror.org/01p19k166

Funder(s)

Funder type
Research organisation

Funder Name
Transfusion and Red Cell Fund TPA007 (UK)

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/07/2014	22/02/2019	Yes	No